UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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In re: PAMIDRONATE PRODUCTS LIABILITY LITIGATION,

NOT FOR PUBLICATION

This Document Relates To:

**MEMORANDUM AND ORDER**
09-MD-2120(KAM)(SMG)

Case No.: 10-CV-1860(KAM)(SMG)
*Bartoli et al. v. APP Pharmaceuticals, Inc. et al.*
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**MATSUMOTO, United States District Judge:**

Presently before the court is a motion to dismiss filed on January 6, 2012 by defendants APP Pharmaceuticals, Inc., Ben Venue Laboratories, Inc. d/b/a Bedford Laboratories, Hospira, Inc., Sandoz Inc., and Teva Parenteral Medicines, Inc. (collectively, "defendants"). Defendants' motion seeks dismissal of the claims of all remaining plaintiffs in this consolidated multi-district proceeding — specifically, Jane Clark (a/k/a Hazel Jane Clark), Marjorie McDonald, Christopher Raso (o/b/o Susan Raso), Sylvia Rose, Karen Shareff, Betty Anne Woodward, Carol Strong (successor: Stacy Strong), Skyla Whaley (o/b/o Doris Whaley), and Cynthia Burke (o/b/o Ed Burke) (collectively, "plaintiffs") — in light of the Supreme Court's opinion in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), *reh'g denied* ("*Mensing*"). (*See* ECF No. 157, Notice of Motion, filed 1/6/2012; ECF No. 158, Memorandum of Law in Support of Defendants' Motion to Dismiss All Remaining Plaintiffs' Claims,

filed 1/6/2012 ("Def. Mem.").)[1] Plaintiffs have not opposed the motion and have indicated that they do not seek to do so.[2] For the reasons that follow, defendants' unopposed motion to dismiss is granted.

**BACKGROUND**

On December 2, 2009, this multi-district litigation ("MDL") was transferred to this court by the United States Judicial Panel on Multidistrict Litigation. (ECF No. 1-3, MDL Transfer Order, filed 12/2/2009.) The MDL Transfer Order described the cases as follows:

> All actions share factual questions relating to generic equivalents of Aredia[3], a brand name prescription drug. Plaintiffs in all actions challenge the safety of these generic equivalents and allege that they developed osteonecrosis of the jaw (ONJ)[4] or have a higher risk for developing ONJ, because of their infusion with those pharmaceutical products.

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[1] Unless otherwise indicated, references to documents filed on the court's electronic case filing system (ECF) refer to docket number 09-md-2120.

[2] By joint letters filed on November 23, 2011 and December 21, 2011, plaintiffs' counsel indicated that plaintiffs would not oppose the instant motion. (*See* ECF No. 148, Joint Letter Regarding Status of Dismissal, dated 11/23/2011, at 2; ECF No. 154, Letter to the Honorable Kiyo A. Matsumoto providing a joint status report, dated 12/21/2011, at 1.)

[3] The generic equivalent of Aredia is called pamidronate. Pamidronate, Drugs.com, http://www.drugs.com/mtm/pamidronate.html (last visited Jan. 30, 2012).

[4] Osteonecrosis is bone death resulting from poor blood supply to an area of bone. Definition of Osteonecrosis, Medterms.com, http://www.medterms.com/script/main/art.asp?articlekey=4682 (last visited Jan. 30, 2012).

(*Id.* at 1.) Plaintiffs are all individuals or their decedents who were given the generic drug pamidronate[5] and developed ONJ. (*See* Case No. 10-CV-1860, ECF No. 10, Second Amended Complaint, filed 1/6/2011 ("Compl.") ¶ 6.) On January 6, 2011, plaintiffs filed a Second Amended Complaint ("Complaint"). (*See id.*) The Complaint alleges that as a result of being infused with generic pamidronate, plaintiffs developed ONJ and suffered injuries. (*Id.* ¶¶ 31-32.) Plaintiffs seek damages from defendants based on theories of design defect, failure to warn, negligence, breach of express warranty, and breach of implied warranty. (*Id.* ¶¶ 33-60.)

On April 26, 2011, defendants served plaintiffs with a motion to dismiss the Complaint, which plaintiffs opposed on June 10, 2011. Following the Supreme Court's decision in *Mensing* on June 23, 2011, this court stayed further briefing on the pending motion to dismiss while the parties considered the impact of that decision and/or whether plaintiffs' claims against defendants would be voluntarily dismissed. (*See* ECF No. 128, Letter Request for Extension of Deadline to File Reply Briefs by APP Pharmaceuticals, LLC, filed 6/27/2011; ECF No.

[5] Pamidronate is in a group of medicines called bisphosphonates. It alters the cycle of bone formation and breakdown in the body. It is used to treat, *inter alia*, high levels of calcium in the blood related to cancer, Paget's disease of the bone, and bone damage caused by certain types of cancer, such as breast cancer and bone marrow cancer. It does not treat cancer itself. Pamidronate, Drugs.com, http://www.drugs.com/mtm/pamidronate.html (last visited Jan. 30, 2012).

130, Letter re Status by APP Pharmaceuticals, LLC, filed 8/8/2011; ECF No. 131, Letter MOTION for Extension of Time to File Response/Reply Brief in Support of Motion to Dismiss by APP Pharmaceuticals, LLC, filed 8/8/2011.) Of the 134 plaintiffs included in the MDL, 125 plaintiffs voluntarily dismissed their claims by December 28, 2011. Pursuant to an Order dated November 25, 2011 (Order dated 11/25/2011), on January 6, 2012, defendants filed the instant motion to dismiss the remaining nine plaintiffs' claims (*see* ECF No. 157, Notice of Motion, filed 1/6/2012; ECF No. 158, Def. Mem.).

## DISCUSSION

### I. Standard of Review

#### A. Motion To Dismiss

Defendants move to dismiss the Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. (*See* ECF No. 158, Def. Mem. at 1.) In considering a motion to dismiss pursuant to Rule 12(b)(6), the court construes the complaint liberally, "accepting all factual allegations in the complaint as true, and drawing all reasonable inferences in the plaintiff's favor." *Chambers v. Time Warner, Inc.,* 282 F.3d 147, 152 (2d Cir. 2002) (citing *Gregory v. Daly,* 243 F.3d 687, 691 (2d Cir. 2001)). In order to survive a motion to dismiss, the complaint must set forth factual allegations sufficient "to raise a right to relief above a speculative level." *Bell Atl.*

*Corp. v. Twombly*, 550 U.S. 544, 555 (2007). The court need not credit "legal conclusions" in the complaint or "threadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Harris v. Mills*, 572 F.3d 66, 72 (2d Cir. 2009) (quoting *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009)) (internal quotation marks and alteration omitted). A motion to dismiss should be granted when, viewing the facts in the light most favorable to the non-moving party, the complaint fails to state a claim upon which relief may be granted.

**B. Law of Preemption**

The Supremacy Clause of the United States Constitution provides that federal law "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. Implied preemption, which is at issue here, occurs when it is "impossible for a private party to comply with both state and federal requirements." *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995) (citation omitted); *accord U.S. Smokeless Tobacco Mfg. Co., LLC v. City of New York*, 703 F. Supp. 2d 329, 334 (S.D.N.Y. 2010). In other words, "[w]here state and federal law 'directly conflict,' state law must give way." *Mensing*, 131 S. Ct. at 2577 (quoting *Wyeth v. Levine*, 555 U.S. 555, 583 (2009) (Thomas, J., concurring in judgment)).

In *PLIVA, Inc. v. Mensing*, plaintiffs brought failure to warn claims under state law against several generic manufacturers of the drug metoclopramide. *Mensing*, 131 S. Ct. at 2573. Plaintiffs alleged that the generic manufacturers violated state tort laws by failing to change the labels for metoclopramide to adequately warn of the risk of a severe neurological disorder. *Id.* The applicable state tort laws required manufacturers that are "or should be aware of [their] product's danger to label that product in a way that renders it reasonably safe." *Id.* The manufacturers, on the other hand, argued that under federal regulations, the generic manufacturers had a duty of "sameness" – that is, "the warning labels of a brand-name drug and its generic copy must always be the same." *Id.* at 2574-75. The Supreme Court held that the plaintiff's failure to warn claims under state law were preempted by federal law because "it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same." *Id.* at 2578.

**II. Application**

Defendants move to dismiss the Complaint, arguing that plaintiffs' state law tort claims are either preempted by federal regulations applicable to generic drugs such as pamidronate or are inadequately pled under federal pleading

standards. (ECF No. 158, Def. Mem. at 1, 10.) The court agrees.[6]

**A. Failure To Warn**

Plaintiffs' claims of failure to warn are squarely preempted by *Mensing*. Plaintiffs claim that defendants "knew or should have known about the possible adverse side effects of pamidronate" but nevertheless failed to satisfy their state law duty to provide "proper warnings regarding possible adverse side effects" of the drug. (Case No. 10-CV-1860, ECF No. 10, Compl. ¶¶ 42-43.) In essence, therefore, plaintiffs' argument is that defendants should have altered the labeling of pamidronate to provide stronger warnings about the drug's possible adverse side effects. However, federal drug regulations "demand[] that generic drug labels be the same at all times as the corresponding brand-name drug labels." *Mensing*, 131 S. Ct. at 2578. If defendants "had independently changed their labels to

[6] In dismissing plaintiffs' claims, the court joins numerous other district courts that have found claims against generic drug manufacturers to be preempted by *Mensing*. *See, e.g.*, *In re Fosamax Prods. Liab. Litig. (No. II)*, MDL No. 2243, Civ. No. 08-008, 2011 U.S. Dist. LEXIS 135006 (D.N.J. Nov. 21, 2011) (dismissing plaintiffs' claims of defective manufacturing, design defect, failure to warn, negligence, breach of implied warranty, and breach of express warranty); *Fullington v. PLIVA, Inc.*, No. 4:10-CV-236, 2011 U.S. Dist. LEXIS 142931 (E.D. Ark. Dec. 12, 2011) (dismissing plaintiff's claims of strict liability, negligence, gross negligence, fraudulent misrepresentation, negligent misrepresentation, fraudulent concealment, and breach of the implied warranties of merchantability and fitness for a particular purpose); *Morris v. Wyeth, Inc.*, No. 3:09-CV-854, 2011 U.S. Dist. LEXIS 121052 (W.D. La. Oct. 19, 2011) (dismissing plaintiff's claims of defective construction or composition, defective design, breach of express warranty, and inadequate warning); *Grinage v. Mylan Pharms., Inc.*, No. 11-cv-1436, 2011 U.S. Dist. LEXIS 149667 (D. Md. Dec. 30, 2011) (dismissing plaintiff's claims of failure to warn, design defect, breach of implied warranty, and fraud).

satisfy their state-law duty, they would have violated federal law." *Id.* Thus, under the Supreme Court's reasoning in *Mensing*, plaintiff's failure to warn claims are dismissed as preempted.

**B. Design Defect**

Plaintiffs' claims alleging defective design are also preempted by federal law. In *Mensing*, the Supreme Court found that a generic drug is "designed to be a copy of a reference listed drug (typically a brand-name drug)" and it must be "identical in active ingredients, safety, and efficacy." *Mensing*, 131 S. Ct. at 2574 n.2. Thus, the "federal duty of 'sameness,'" *id.* at 2575, also applies in the context of generic drug design, and federal law preempts state laws imposing a duty to change a drug's design on generic drug manufacturers, *see In re Fosamax Prods. Liab. Litig. (No. II)*, MDL No. 2243, Civ. No. 08-008, 2011 U.S. Dist. LEXIS 135006, at *33-34 (D.N.J. Nov. 21, 2011) (finding state law design defect claims preempted pursuant to *Mensing*); *Stevens v. PLIVA, Inc.*, 6:10-0886, 2011 U.S. Dist. LEXIS 147684, at *5-6 (W.D. La. Nov. 15, 2011) (same). Accordingly, plaintiffs' design defect claims are dismissed.[7]

[7] Plaintiffs' allegations of design defect also fail because they are not supported by factual allegations in the Complaint. Plaintiffs allege that pamidronate was defectively designed because it was "unreasonably dangerous" and "its foreseeable risks exceed the benefits associated with the design or formulation." (Case No. 10-CV-1860, ECF No. 10, Compl. ¶¶ 35-36.) Plaintiffs do not describe the nature of the purported design defect or how such defect caused plaintiffs' injuries. Such "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do

**C. Negligence**

Plaintiffs allege that defendants "failed to exercise reasonable care in testing, manufacturing, labeling, marketing, distributing and selling pamidronate . . . ." (Case No. 10-CV-1860, ECF No. 10, Compl. ¶ 48.) First, allegations that the labeling, marketing, distributing, and selling of pamidronate failed to meet a certain standard of reasonable care are preempted pursuant to *Mensing* because these allegations are in essence failure to warn claims.

Second, plaintiffs' allegations of negligence based on the failure to exercise reasonable care in testing and manufacturing pamidronate fail because the Complaint merely makes a conclusory allegation of negligence, without any factual support for this cause of action. Indeed, the factual allegations as to wrongdoing by defendants contained in paragraphs 23 through 30 of the Complaint are all allegations that defendants knew of the potential adverse effects of pamidronate and provided inadequate information regarding the harm that pamidronate may cause. (*See id.* ¶¶ 23-30.) Thus, plaintiffs have provided no more than a "sheer possibility" that defendants defectively tested and manufactured pamidronate.

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not suffice" to state a claim. *Iqbal*, 129 S. Ct. at 1949; *see also Fullington*, 2011 U.S. Dist. LEXIS 142931, at *15 (granting generic drug manufacturers' motion to dismiss where plaintiffs' allegations of design defect were conclusory).

*Iqbal*, 129 S. Ct. at 1949. Plaintiffs' "formulaic recitation of the elements of a cause of action will not do." *Id.* (citing *Twombly*, 550 U.S. at 555). Thus, plaintiffs' claims that defendants were negligent are dismissed.

**D. Breach of Express Warranty**

Plaintiffs' claim based on breach of express warranty is in essence a failure to warn claim, and thus is preempted pursuant to *Mensing*. Plaintiffs allege that defendants made false statements or representations that pamidronate was "safe, effective, and fit for its intended uses." (Case No. 10-CV-1860, ECF No. 10, Compl. ¶ 52.) Plaintiffs attack the accuracy of these representations by alleging that pamidronate "caused serious adverse side effects, including ONJ." (*Id.* ¶ 54.) This claim suggests that defendants should have changed or omitted the allegedly inaccurate statements.

Federal law, however, forbids a generic drug manufacturer from unilaterally changing, omitting, or strengthening drug labeling. *See Mensing*, 131 S. Ct. at 2578 ("[S]tate law imposed on the Manufacturers a duty to attach a safer label to their generic [drug]. Federal law however, demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels."). Here, defendants could not unilaterally change their pamidronate labels pursuant to state law and simultaneously comply with their federal law

duty of sameness. Accordingly, plaintiffs' breach of express warranty claims are preempted and dismissed.

**E. Breach of Implied Warranty**

Plaintiffs' breach of implied warranty claims are also preempted. Plaintiffs allege that defendants "impliedly warranted to Plaintiffs and/or their decedents . . . and/or their agents, that pamidronate was of merchantable quality and was safe and fit for its intended uses," but that the drug "was not of merchantable quality or safe and fit for its intended uses . . . ." (Case No. 10-CV-1860, ECF No. 10, Compl. ¶¶ 57, 59.) Because this cause of action is founded on the argument that pamidronate should have been designed differently, it fails for the same reasons previously explained in the court's analysis of the design defect claims. Plaintiffs' breach of implied warranty claim necessarily alleges that defendants should have changed the design of pamidronate to make it "safe and fit for its intended uses." (*Id.* ¶ 59.) Pursuant to defendants' "federal duty of 'sameness,'" *Mensing*, 131 S. Ct. at 2575, however, defendants were prohibited by federal law from changing the design of pamidronate. Thus, plaintiffs' breach of implied warranty claims are preempted and dismissed.

## CONCLUSION

For the reasons stated above, defendants' motion to dismiss the claims of all remaining plaintiffs is granted. The Clerk of Court is respectfully requested to enter judgment and close the case.

**SO ORDERED.**

DATED: Brooklyn, New York
January 30, 2012

/s/
**Kiyo A. Matsumoto**
United States District Judge
Eastern District of New York